DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 21, 2016

Beijing Choice Electronic Technololgy Co., Ltd.
Lei Chen
Quality Director
No.9 Shuangyuan Road, Badach Hi-tech Zone
Shijingshan District
Beijing, 100041 CN

Re: K160508
Trade/Device Name: Electronic Pulse Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: February 22, 2016
Received: February 24, 2016

Dear Lei Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.11.21 21:22:10 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Section II Indications for Use Statement

## Indications for Use

510(k) Number (if known): _____

Device Name: Electronic Pulse Stimulator

Model: MDTS100

Indications for Use:

The Electronic Pulse Stimulator MDTS100 is to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household and work activities.

| Prescription Use _____ | AND/OR | Over-The-Counter Use √ |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | | (21 CFR 801 Subpart C) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

## 3.1 Submitter Information

**Manufacturer Name:**
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**Date prepared：October 31, 2016**

## 3.2 Proposed Device Information

**Device Common Name:** Transcutaneous Electrical Nerve Stimulator, OTC

**Device Trade/Proprietary Name:** Electronic Pulse Stimulator

**Model:** MDTS100

**Classification Name:** Transcutaneous Electrical Nerve Stimulator for pain relief

**Regulation Number:** 21 CFR 882.5890

**Product Code:** NUH

**Class:** II

**Use:** Over -The-Counter Use

**Panel:** Neurology

## 3.3 Predicate Device

**510(k) Number:** K122744

**Common Name:** Transcutaneous electrical nerve stimulator OTC

**Device Trade/Proprietary Name:** Prospera OTC TENSE Electronic Pulse Massager

**Model: PL029**

**Classification Name:** Transcutaneous Electrical Nerve Stimulator for pain relief

**Product Code:** NUH, NGX

**Regulation Number:** 21 CFR 882.5890

**Device Class:** II

**Panel:** Neurology

**Use:** Over-The-Counter Use

**Manufacturer:** Prospera Corporation

**Intended Use:**

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities(arm), and lower extremities(leg) due to strain from exercise or normal household work activities.

## 3.4 Device Description

The MDTS100 Electronic Pulse Stimulator is an electrically powered device intended for over the counter use and used to apply an electrical current to electrodes on a user's skin to relieve pain. The proposed device is intended for at home use in delivering electric pulses to tired and sore muscles.

The proposed device consists of controlling host device, output connecting cable and skin electrodes. The proposed device has many safety measures such as output load detection, timing indication and so on. It is adopted battery as the power supply. The output waveform is adopted "square waveform" as the basic wave. It simulates the various output modes by various frequency combination. The waveform is mainly for single rectangular. The output waveform intensity is continuous adjustable. The working time is controlled automatic.

The MDTS100 is adopted the method that inputting the specific low frequency pulse

current into the human body through the human skin to treat the pain.

The MDTS100 Electronic Pulse Stimulator has seven stimulation modes. These stimulation modes can be selected by pressing the MODE button on the front of the unit.

The MDTS100 comes with 2 independent output channels by pressing the CHA button. Channel A&B are selected by default. Pressing the ◁ & ▷ buttons will decrease & increase the intensity of stimulation. LCD screen display the left remaining stimulation time in the lower left corner. The default time is 20 minutes.

The proposed device is not for life-supporting or life-sustaining, not for implant.

The device is not sterile and the transducers are reusable and do not need sterilization and re-sterilization.

The device is for over the counter use.

The device does not contain drug or biological products.

The device is software-driven and software validation is provided in ***software***.

## 3.5 Indication for Use

The Electronic Pulse Stimulator MDTS100 is to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household and work activities.

## 3.6 Comparison list of technical characteristics

Table 3-1 Basic Unit Characteristics Comparison Table between the Proposed Device (MDTS100) and Predicate Device

| **Parameter** | | **Proposed Device** | **Predicate Device** |
|---|---|---|---|
| 510(k) number | | (to be assigned) | K122744 |
| Device Name and Model | | MDTS100 | PL029 |
| Manufacturer | | Beijing Choice Electronic Technology Co., Ltd. | Prospera |
| Power Source | | DC 3V, 2 AAA batteries | 3V Battery |
| -Method of Line Current Isolation | | N/A for DC current | Battery Supply N/A |
| -patient Leakage Current | | -- | --- |
| -Normal Condition(μA) | | ≤10μA | 2.0μA |
| -Single Fault Condition(μA) | | ≤50μA | 3.0μA |
| Average DC current through electrodes when device is on but no pulses are being applied(μA) | | ≤10μA | 0μA |
| Number of Output Modes | | 7 | 8 |
| Number of Output Channels | Synchronous or Alternating? | Alternating | Alternating |
| | Method of Channel Isolation | No | By software |
| Regulated Current or Regulated Voltage? | | Regulated Voltage | Voltage control |
| Software/Firmware/Microprocessor Control? | | Yes | Yes |

| | | | |
|---|---|---|---|
| Automatic Overload Trip? | | No | No |
| Automatic No-Load Trip? | | Yes | No |
| Automatic Shut Off? | | Yes | Yes |
| User Override Control? | | Yes | Yes |
| Indicator Display: | On/OFF Status? | Yes | Yes |
| | Low Battery? | Yes | No |
| | Voltage/Current Level? | Yes | No |
| Timer Range (minutes) | | 20 minutes | 5minutes, 10 minutes |
| Compliance with Voluntary Standards? | | Yes | Yes |
| Compliance with 21 CFR 898? | | Yes | Yes |
| Weight (lbs., oz.) | | 0 lb., 2.2 oz. ( Battery Excluded ) | 0 lb, 8.21oz. |
| Dimensions (in.) [W x H x D] | | 2.17x 5.12x0.87 | 2.24x7.87x0.83 |
| Housing Materials and Construction | | Enclosure: ABS | Enclosure: ABS |

Table 3-2 Output Specification Comparison Table between the Proposed Device (MDTS100) and Predicate Device

| **Parameter** | **Proposed Device** | **Predicate Device** |
|---|---|---|
| Device Name and Model | MDTS100 | PL029 |
| Waveform | pulsed monophasic | Monophasic |
| Shape | Rectangular | Rectangular |
| Maximum Output Voltage (volts) (+/- 20 %) | 150V@500 Ω | 49.6V@500 Ω |
| | 160V @2k Ω | 99.2V@2k Ω |
| | 165V@10k Ω | 114V @10k Ω |
| Maximum Output Current (specify units) (+/- 20 %) | 300mA @500 Ω | 18mA @500 Ω |
| | 80mA @2k Ω | 3.2mA@2k Ω |

| | | | |
|---|---|---|---|
| | | 16.5mA @10kΩ | 0.6mA @10kΩ |
| Duration of primary (depolarizing) phase (μsec) | | 0μsec | 40msec |
| Pulse Duration (μsec) | | 50~140μsec | 120~6800μsec |
| Frequency (Hz) [or Rate (pps)] | | 0.9Hz~82Hz | 0.5~86Hz |
| Net Charge (microcoulombs (μC) per pulse) @500Ω | | 42μC | 18000μC |
| Maximum Phase Charge, (μC) @500Ω | | 42μC | 23μC |
| Maximum Current Density, (mA/cm2, r.m.s.) | | 3.3mA/cm2@1.57″×1.57″Electrode Pad | 1.4mA/cm2 |
| Maximum Average Current (average absolute value), mA | | 2.8mA | --- |
| Maximum Average Power Density, (W/cm2), (using smallest electrode conductive surface rate) | | 0.02W/cm2@1.57″×1.57″Electrode Pad | 0.23 W/cm2 |
| Burst Mode | (a) Pulses per burst | 197 | 1 |
| | (b) Burst per second | 0.185 | 0-7 |
| | (c) Burst duration (seconds) | 2.4s | 1 |
| | (d) Duty Cycle: Line(b) x Line(c) | 0.44 | 7 |
| ON TIME (seconds) | | ≤1second | 40ms |
| OFF TIME (seconds) | | ≤1second | 18ms |
| Additional Features | | --- | --- |

**Conclusion:** The data in Table 3-1 and Table 3-2 indicates that the technical characteristics, features, specifications and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle areas. Outputs are almost the identical, each can produce square electronic pulses and positive-going waveform output. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both devices are transiting pulses by the use of Electrode Pads. Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicated device. The parameters such as waveform, frequency, pulse width, output current and voltage, although not exactly similar to this particular predicate, they do not raise any new questions of safety or effectiveness. The differences that exist between the devices are insignificant in terms of safety and effectiveness.

## 3.7 Functional and Safety Testing:

Non-clinical tests were performed on the subject matter device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medial device electrical safety, electromagnetic compatibility, and particular requirements for the safety of nerve and muscle stimulator:

**EMC and electrical Safety**

IEC 60601-1:2005 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic compatibility-Requirements and tests.

IEC 60601-1-11: 2010 Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-2-10: 2012Medical electrical equipment-Part 2-10: Particular requirements for the safety of nerve and muscle stimulator.

**Biocompatibility**

The electrode pads are the mainly body contacting parts. Electrode pads, as accessories of the subject matter device, are adopted the Self-adhesive Electrode manufactured by Wuxi Jiajian Medical Instrument Co., Ltd. and have been cleared by FDA in June 23, 2009 as K090198. The patient contacting electrodes comply with ISO 10993 and are considered Class A ≤24 hours contact.

**Software**

In addition to the compliance of voluntary standards, the software verification has been carries out according to the FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.

**Cleaning**

The cleaning instructions as described in the Instruction Manual have been tested to be sufficient. The test result was presented in the system test report in Performance Testing.

## 3.8 Conclusion

The Electronic Pulse Stimulator MDTS100 has the similar intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and

effectiveness as that of the predicate device. In other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the proposed device MDTS100 is substantially equivalent to the predicate device.